REMARKS

Claims 24-33 and 35-48 are pending in the instant application. Claims 24-33 and 35-48 have been rejected. Claims 24, 32, 33, 41 and 46 have been amended. Claim 31 has been canceled. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Rejections Under 35 U.S.C. §112

Claim 24 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particular point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, it is suggested that the Markush group of claim 24 is improper because the broadest interpretation of "neutral oil" is that of "an oil that does not react, or interfere with the composition it is in." The Examiner acknowledges that the specification discloses that "neutral oil (Miglyol) is understood to mean a mixture of short- and medium-chained triglycerides, mainly with the fatty acids caprylic acid (C8) and capric acid (C10);" however the Examiner contends that the term "neutral oil" is a functional limitation and various oils listed in the Markush group are considered neutral oils.

Applicants respectfully disagree with this rejection. While it is the Examiner's contention that "neutral oil" is defined as "an oil that does not react, or interfere with the composition it is in," (page 5, section 11 of the Office Action), the Examiner has not provided any evidence of record to substantiate this definition of neutral oil. Indeed, the Examiner has not provided sufficient evidence to show that, in view of the Specification,

the skilled artisan would not be apprised of the scope of the claims.

MPEP 2111 instructs:

During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." [emphasis added] The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard:

> The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004).

In this respect, the skilled artisan would clearly understand a neutral oil as comprising caprylic and capric acid triglycerides as defined at page 9, ¶5 of the instant specification. However, in the interest of facilitating the prosecution of this application, Applicants have amended the claims to specify the chemical composition of a neutral oil as comprising caprylic and capric acid triglycerides as supported by the disclosure at page 9, ¶5 of the instant specification. In light of this amendment, the skilled artisan would be clearly apprised of the scope of a neutral oil according to the present invention. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

II. Rejections Under 35 U.S.C. §102

Claims 24-31, 35, 38, 40-43 and 45-48 remain rejected under 35 U.S.C. 102(b) as being anticipated by Price et al. (US 4,128,658) for the reasons of record.

Applicants respectfully traverse this rejection. In the reply filed December 31, 2008, independent claims 24, 41, and 46 were amended to specify that the oily substance is selected from the group of neutral oil, sesame oil, peanut oil, olive oil, almond oil, soybean oil, coconut oil, cottonseed oil, corn oil, rape oil, sunflower oil, wheat kernel oil liquid paraffin, wax solutions in organic oil, and low viscosity wax. Moreover, as currently presented, a neutral oil comprises caprylic and capric acid triglycerides. As noted by the Examiner at page 7, ¶1 of the Office Action, CUTINA HR is hydrogenated castor oil. Castor oil is composed of ricinoleic, oleic, linoleic, lauric, myristic, palmitic and stearic acids (*see* National Non-Foods Crop Center description of Castor, enclosed herewith); however, castor oil does not comprise caprylic and capric acid triglycerides as required by the instant neutral oil nor is castor oil a sesame oil, peanut oil, olive oil, almond oil, soybean oil, coconut oil, cottonseed oil, corn oil, rape oil, sunflower oil, wheat kernel oil liquid paraffin, wax solutions in organic oil, or low viscosity wax.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson*

v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). See MPEP 2131.

In this respect, nowhere do Price et al. teach or suggest granules or methods for preparing the same using the oily substances as presently claimed. Thus, this reference cannot be held to anticipate the subject matter of the present invention. Therefore, it is respectfully requested that this rejection under 35 U.S.C. 102(b) be withdrawn.

Claims 24-25, 28-30, 35-36, and 45-47 have been rejected under 35 U.S.C. 102(b) as being anticipated by Fuisz (US 5,387,431). The Examiner contends that Example 16 anticipates the present invention by disclosing the preparation of a pharmaceutical product by mixing an active ingredient (sucralfate) with a retardant (xanthan gum), corn oil and maltodextrin, wherein the corn oil will "wet" the dry powders, and the step of subjecting the mixture to conditions of force and temperature is considered to anticipate the step of granulation.

Applicants respectfully disagree with this rejection. As described at page 7, ¶8 of the instant specification, it has been found that adequate retardation and good processability of an active ingredient can be achieved by means of granulating processes when a mixture of active ingredient(s) and lipophilic retarding agent(s) are combined with an oily substance prior to or during granulation. While Fuisz may suggest combining sucralfate, xanthan gum, corn oil and maltodextrin, the cited passages of this reference do not teach or suggest wetting a mixture of one or more active ingredients and one or more *lipophilic* retarding agents with an oily substance. Thus, in an earnest effort to highlight the characteristics of the instant

retarding agents, Applicants have amended claims 24 and 41 to specify that the retarding agents are lipophilic. In so far as this amendment is directly supported by claim 31, claim 31 has been canceled, and claims 32 and 33 have been amended to be dependent from claim 24. Because Fuisz fails to teach or suggest each and every limitation of the claims as currently presented, this reference cannot be held to anticipate the same. It is therefore respectfully requested that this rejection under 35 U.S.C. 102(b) be withdrawn.

III. Rejections Under 35 U.S.C. §103

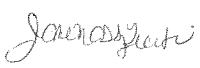
Claims 32-33, 36-37, 39 and 44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Price et al. (US 4,128,658) in view of Santus et al. (US 5,472,704) for the reasons of record.

Applicants respectfully traverse this rejection. The courts have held, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). As discussed above, Price et al. fail to teach the use of the oily substances set forth in the claims as currently presented. In so far as Santus et al. fail to compensate for the deficiencies in the teachings of the primary reference, the combined teachings of Price et al. and Santus et al. cannot be held to make the present invention obvious under 35 U.S.C. 103(a). It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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Date: **June 29, 2009**

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